K060963

JUN - 6 2006

Twin Star Medical, Inc.

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510(k) SUMMARY

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Date of Submission:	March 28, 2006
Submitter:	Twin Star Medical, Inc.
Address:	1000 West Gate Drive, Suite 117 St. Paul, MN 55114
Contact:	Chet Sievert
Phone:	651.246.8621
Fax:	651.209.0556
Common Name of Device:	Pressure Monitor
Proprietary Device Name:	Twin Star Compartment Pressure Monitoring and Fluid Collection Monitor (CMS Monitor)
Classification Name:	Monitor, Pressure, Intracompartment
Predicate Devices:	Stryker Corporation Intracompartmental Syndrome Pressure Monitor System (K844214) Medela Corporation Median Vacuum Pump (K983552)

Description of the Device

The Twin Star Compartment Pressure Monitoring and Fluid Collection (CMS) Monitor displays and records pressure as measured by the Twin Star Compartment Pressure Monitoring and Fluid Collection Catheter (CMS Catheter). The Twin Star CMS Catheter has been previously cleared by 510k notification. The multi-task CSM Monitor consists of a single housing unit that incorporates a vacuum pump, an infusion pump and a pressure monitor with visual display and user interface. The CMS Monitor provides the necessary functions required by the CMS Catheter. In addition to monitoring pressure, the CMS Monitor provides a very low volume fluid infusion to maintain the CMS Catheter's pressure lumen patency and a vacuum to the second lumen for fluid collection; both infusion and vacuum are required for the functional operation of the CMS Catheter.

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Intended Use

The Twin Star Compartment Pressure Monitoring and Fluid Collection Monitor (CMS Monitor) is intended for the measurement and monitoring of intracompartmental pressures and the withdrawal of fluid for subsequent analysis. The measured compartmental pressures can be used as an aid in the diagnosis of compartment syndrome. The CMS Monitor is intended to be used in conjunction with the Twin Star Compartment Pressure Monitoring and Fluid Collection Catheter (CMS Catheter).

Comparison of Technical Characteristics

The Twin Star CMS Monitor is equivalent to the Stryker Intracompartmental Syndrome Pressure Monitor System in that it has the same indications for use, the same target patient population and the same technical characteristics including a fluid filled pressure measuring catheter, a pressure monitor and a method of fluid infusion to maintain catheter patency. The only significant difference between the Twin Star CMS Monitor and the Stryker predicate is fluid removal using a vacuum. A predicate device that provides a vacuum for fluid removal is the Medela Median Vacuum Pump. The Medela predicate removes fluid via a vacuum pump with similar indications for use, similar patient populations and similar technical characteristics. The administration of therapy is essentially the same between the Twin Star CMS Monitor and the predicates.

Performance Testing

Functional and performance testing was performed on the Twin Star CMS Monitor and its predicates. The results of measuring pressure, infusion and vacuum capabilities were compared. It was statistically proven that the performance of the Twin Star CMS Monitor was substantially equivalent to the performance of the predicate devices.

Conclusion/Substantial Equivalence

The Twin Star CMS Monitor has the same intended use compared to the Stryker predicate i.e., for monitoring intracompartment pressure as an aid in the diagnosis of compartment syndrome. Both the predicate and the proposed monitors utilize fluid infusion as a method of maintaining catheter patency to insure measurement accuracy. Performance testing has demonstrated equivalent results. The CMS Monitor provides a vacuum capability that the Stryker predicate does not. The CMS Monitor has a substantially equivalent intended use compared to the Medela predicate i.e., for vacuum pump removal of bodily fluids from wounds at the patient's bedside. Performance testing has demonstrated equivalent results.

Therefore, by claiming similar intended uses, similar patient populations and by demonstration of equal performance it is concluded that the CMS Monitor is substantially equivalent to the identified predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2006

Twin Star Medical, Inc.
% Mr. Chet Sievert
Regulatory Affairs
1000 Westgate Drive, Suite 117
St. Paul, Minnesota 55114

Re: K060963
Trade/Device Name: Twin Star Compartment Pressure Monitoring and Fluid Collection Monitor (CMS Monitor)
Regulatory Class: Unclassified
Product Code: LXC
Dated: March 29, 2006
Received: April 7, 2006

Dear Mr. Sievert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

INDICATIONS FOR USE

510(k) Number: Not known K060963

Device Name: Twin Star Compartment Pressure Monitoring and Fluid Collection Monitor (CMS Monitor)

Indications for Use:

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...ivision of General, Restorative,
...d Neurological Devices

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Prescription Use **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use **NO** (21 CFR 801 Subpart C)